

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
Anti-Infective Drugs Advisory Committee Meeting  
Hilton Washington DC/Gaithersburg  
December 9, 2009

**AGENDA**  
**OPEN SESSION**

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*The committee will discuss endpoints and other clinical trial design issues in the development of antibacterial products for the treatment of community-acquired bacterial pneumonia.*

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8:00 – 8:15 a.m.	<b>Call to Order &amp; Introduction of Committee</b> Committee Chair
	<b>Conflict of Interest Statement</b> Minh Doan, Pharm.D., Designated Federal Officer
8:15 – 8:30 a.m.	<b>Background</b>
8:30 – 9:00 a.m.	<b>Summary of Prior Discussions</b>
9:00 – 9:30 a.m.	<b>Historical Evidence</b>
9:30 – 10:00 a.m.	<b>Current CABP Guidance and Comments Received</b>
10:00 – 10:15 a.m.	Break
10:15 – 11:00 a.m.	<b>Guest Speaker Presentation</b>
11:00 – 11:15 a.m.	<b>Path Forward</b>
11:15 – 11:45 a.m.	Questions/Clarifications
11:45 a.m. – 12:45 p.m.	Lunch
12:45 – 2:15 p.m.	Open Public Hearing
2:15 – 3:30 p.m.	Discussion
3:30 – 3:45 p.m.	Break
3:45 – 5:30 p.m.	<b>Charge and Questions to the Committee</b>
5:30 p.m.	Adjourn